

### **REMARKS/ARGUMENTS**

Applicant thanks the Examiner for the rejoinder of Groups I and II.

Claims 1-28 are pending in this application. Claims 1-8 and 10-19 are currently under consideration, and claims 9 and 20-28 are withdrawn. Claim 4 has been canceled and, claims 1 and 15 have been amended to incorporate the feature of former claim 4. Claims 2, 5 and 7 have been amended in light of the amendments to claim 1 or to adjust the claim dependencies. Claims 12 and 13 have been amended in accordance with the Examiner's comments.

Particularly, claims 1 and 15 have been amended to specify that the microparticle comprises a carbamate and a mixture comprising first and second biodegradable polymers, wherein one of the polymers is more hydrophobic than the other polymer. Support for this amendment is found at least in claim 4 and in paragraph [0029] of the application as originally filed. Claims 2 and 7 have been amended to indicate that the first or second biodegradable polymer is as specified in the respective claim. Support for these amendments is found at least at paragraphs [0024] and [0029] of the application as originally filed. Amendment to the claim dependency of claim 5 is found in claim 4 as originally filed

As indicated in the present application, selection of a mixture of biodegradable polymers where one polymer is more hydrophobic than another polymer in the mixture allows for control of the degree of the initial burst release from the microparticles.

#### **Claim Objections**

The Examiner objected to claim 12 on the basis that the values given for the molecular weight range were missing commas. Claim 12 has been amended accordingly, as suggested by the Examiner. Applicant respectfully requests withdrawal of this objection.

#### **Claim Rejections 35 USC 112**

The Examiner rejected claim 13 on the basis that this claim contained subject matter not described in the specification. This claim has been amended to indicate that the specified

concentration of the polymer is the concentration of the polymer in a solvent mixture prior to forming the microparticle from the solvent mixture, as suggested by the Examiner. Applicant respectfully requests withdrawal of this rejection.

### **Claim Rejections 35 USC 102**

The Examiner rejected claims 1-8, 10-13, 15-16 and 18-19 under 35 USC 102(b) as being anticipated by Roorda *et al.*

Applicant respectfully submits that Roorda *et al.* does not anticipate the claims as amended, for at least the following reasons.

Roorda *et al.* does indicate that a mixture of bioerodible [biodegradable] polymers may be used, the reference makes only general statements to this effect. See for example column 4, lines 11 and 12 and column 4, lines 51 to 58 of the reference. The reference does not specify that the polymers in the mixture are chosen such that one polymer is more hydrophobic than another polymer. Although a physical mixture of polymers A and B is disclosed, these polymers will have almost identical hydrophobicity, given that each is a poly(dioxy tetrahydrofuran) orthoester having either a cyclo-alkyl (polymer A) or straight-chain alkyl (polymer B) segment.

Nor does Roorda *et al.* teach, suggest or disclose that adjusting the hydrophobicity of polymers used in a mixture in microparticles allows for control or adjustment of the initial burst release from the microparticles. Rather, Roorda *et al.* teaches that the release rate from the described device is primarily independent of the rate of erosion of the polymer matrix and is dependent on the amount of required excipient included in the device [microparticle] of Roorda *et al.*

Thus, Applicant respectfully submits that the claims as amended are not anticipated by the Roorda *et al.* reference, and respectfully requests withdrawal of this rejection.

The Examiner rejected claims 1-8 and 10-19 under 35 USC 102(e) as anticipated by Gao *et al.*

Applicant respectfully submits that Gao *et al.* does not anticipate the claims as amended, for at least the following reasons.

Gao *et al.* does not teach a microparticle comprising a mixture of biodegradable polymers. Rather, this reference describes a layered particle, in which the active ingredient is included in a “monolithic” single polymer core; the polymer core is then coated with a NaCl-loaded polymer film, which film acts to control the release rate of the active ingredient from the polymer core. This reference does not teach, suggest, or otherwise disclose the use of a mixture of biodegradable polymers in a microparticle, and particularly does not teach, suggest or otherwise disclose a mixture of biodegradable polymers in which one biodegradable polymer is more hydrophobic than another biodegradable polymer.

Thus, Applicant respectfully submits that the claims as amended are not anticipated by the Gao *et al.* reference, and respectfully requests withdrawal of this rejection.

### **Claim Rejections 35 USC 103**

The Examiner rejected claims 1-9 and 11-18 under 103(a) as obvious having regard to Roorda *et al.* The basis for this rejection appears to be based on specification of the amount of physostigmine in the claims.

Applicant respectfully points out that claim 9 is currently withdrawn as being directed to a non-elected species, pyridostigmine. Applicant assumes that this rejection was intended to be directed to claims 14, 17 and 18, which claims specify a carbamate concentration of 10% w/w. If this is not the case, Applicant requests that the Examiner clarify his position.

Applicant respectfully disagrees that the claims as amended are obvious having regard to the Roorda *et al.* reference, for at least the following reasons.

As stated above, Applicant submits that the Roorda *et al.* reference does not teach or even suggest a microparticle comprising a mixture of biodegradable polymers, in which one

biodegradable polymer is more hydrophobic than another biodegradable polymer in the mixture. As stated above, Roorda teaches that the release rate of the active ingredient is dependent on the amount of a required excipient, such as cholesterol, included in the particle. Since there is no disclosure or suggestion in Roorda *et al.* of the invention as described in independent claims 1 and 15, the subject matter of the dependent claims, including claims 14, 17 and 18, cannot be rendered obvious by the Roorda *et al.* reference.

Thus, Applicant respectfully requests withdrawal of the rejection under 35 USC 103 based on Roorda *et al.*

It is believed no new matter has been added by these amendments. In view of the foregoing, Applicant respectfully requests withdrawal of the claim objections and rejections and favorable reconsideration of the application.

Respectfully submitted,

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